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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,130	03/01/2001	Kakuji Torigoe	TORIGOE-4	8207

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,130	TORIGOE ET AL.	
	Examin r	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment in paper No. 13, filed on 24 March 2003 is acknowledged and entered. Following the amendment, claims 1-9 are amended, and the new claim 10 is added.

Currently, claims 1-10 are pending and under consideration.

Withdrawal of Objections and Rejections:

The objection of claims 1, 2 and 6 for encompassing a non-elected subject matter is withdrawn in view of applicant's amendment.

The rejection of claims 1-7 under 35 U.S.C. 101 for claiming non-statutory subject matter is withdrawn in view of applicant's amendment.

The rejection of claims 1, 3, 4 and 7-9 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

The prior art rejection of claims 5 and 6 under 35 U.S.C. 102(b) as being anticipated by Adams et al. for locus AA311795 is withdrawn in view of applicant's amendment.

Formal Matters:

Applicant is advised that should claim 7 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 9 is objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends from claim 8, which is drawn to a composition. In this case, the recited intended use does not appear to narrow the scope of the claimed composition.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the last Office Action, paper No. 12, mailed on 22 October 2002, at pages 2-3.

Applicants argument, filed on 24 March 2003 (paper No. 13) has been fully considered, but is not deemed persuasive for reasons below.

The claim has been amended to recite "4 to 29 contiguous amino acid residues by ...". At page 6 of the response, the applicant pointed out the support of such a limitation in the specification, at pages 18-19, Example 1-3. This is not persuasive because the disclosure pointed out by applicants is merely technical details for analytical purpose, i.e., several fragments of the polypeptide were generated as a result of trypsin digestion for the purpose of peptide mapping. Such random fragments by enzymatic digestion are not considered a disclosure *for an invention* because they do not serve any specific purpose other than analytical peptide mapping, and were not disclosed as being an inventive concept.

The new claim 10 is rejected for the same reasons above.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 5, the newly amended claim recites the limitation of "said DNA does not consist of nucleotide residues 35 to 485 of SEQ ID NO:32". However, applicants have

not pointed out, nor can the Examiner locate, the basis in the specification for a DNA not consisting of nucleotides *35 to 485* of SEQ ID NO:32. This is a new matter rejection.

With respect to claim 6, the newly amended claim recites the limitation "a homology higher than 61% to the amino acid sequence of SEQ ID NO:1". While the specification, as applicants pointed out, teaches that the amino acid sequence of the IL-18BP of human origin (SEQ ID NO:1 exhibited about 61% homology with the amino acid sequence of (encoded by?) SEQ ID NO:41, which is the mouse IL-18BP (note: SEQ ID NO:41 is a nucleic acid sequence), it is not a limitation indicating that a nucleic acid having a homology of higher than 61% to the amino acid sequence of SEQ ID NO:1 is a IL-18BP, nor does it suggest a invention of a DNA encoding a polypeptide having a homology of higher than 61% to SEQ ID NO:1, and IL-18 binding activity. As such, the new amendment of "higher than 61%" defines a new concept of the invention, which is not supported by the original disclosure. This is a new matter rejection.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains indefinite because it is unclear what is *a functional fragment of IL-18* as IL-18 has multiple functional activities, and the specification does not define such. The metes and bounds of the claim, therefore, cannot be determined. Amendment to "an IL-18 binding fragment" would be remedial. The claim is further indefinite as SEQ ID NO:1 is not IL-18.

Claim 2 recites the limitation "the purified interleukin-18-binding protein of claim 1" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim as claim 1 merely recites "a purified interleukin-18". Claims 3-5, 7 and 8 are similarly indefinite.

Claim 6 remains indefinite for the recitation of "the DNA of claim 5, which comprises the nucleotide sequence of SEQ ID NO:32". As claim 5 is drawn to a DNA ... with the proviso that said DNA does not consist of nucleotide residues 35-485 of SEQ ID NO:32, it is unclear

how the DNA of claim 6 comprises SEQ ID NO:32. The claim is further indefinite for the recitation of "homologous to said *nucleotide sequence*, which has a homology of higher that 61% to the *amino acid sequence* of SEQ ID NO:1", as it is improper to compare a nucleotide sequence with an amino acid sequence.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5 and 6 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an IL-18 binding protein having SEQ ID NO:1, functional fragments thereof, and the DNA encoding SEQ ID NO:1, does not reasonably provide enablement for claims to all IL-18 binding proteins which comprise small fragments of SEQ ID NO:1 (claims 2 and 10), and DNA encoding the variants or homologues thereof (claims 5 and 6). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons set forth in the last Office Action, paper No. 12, at pages 4-5.

Applicants argument paper No. 13 has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, applicants argue that claim 2 is dependent from claim 1, and therefore, it is readily understood that the "4 to 29 contiguous amino acid residues" in claim 2 naturally possess IL-18 binding ability. This argument is not persuasive because, as addressed in the previous Office Action, given the fact that the IL-18BP polypeptide of the present invention has 164 amino acids, a fragment of 4 amino acids, even within a functional domain is unlikely to possess any desired biological activity, such as that claimed. The specification merely discloses several small fragments resulted from trypsin digestion of the polypeptide, and no functional activity was ever tested in these fragments. Further, the specification provides neither guidance, nor working example as to how to use these fragments. Therefore, it is unpredictable whether

the claimed fragments would have any functional activity, and it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use such fragments for any purpose stated in the specification.

There is no further argument to sustain the issue associated with other rejected claims.

The amendment of claims 5, 6, and 10 raises new enablement issues, such as variants of the claimed IL-18BP, which are not addressed herein because they constitute new matter. However, the issues will be reinstated if new matter rejection is removed.

Claims 2, 5 and 6 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the last Office Action, paper No. 12, at pages 6-7.

Applicants argument paper No. 13 has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, applicants argue that the specification discloses SEQ ID NO:3-23 as 21 concrete examples of functional fragments of SEQ ID NO:1, and accordingly provides adequate written description of the claimed invention. This argument is not persuasive because, as addressed above, the specific fragments disclosed in the specification were generated as a result of trypsin digestion for the purpose of peptide mapping. Such random fragments by enzymatic digestion are not considered a disclosure *for an invention* because they do not serve any specific purpose other than analytical peptide mapping. Additionally, no functional test was ever performed for these fragments. Therefore, they are, by no means, "functional" fragments.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 remain rejected, and claims 7-9 are under 35 U.S.C. 103(a) as being unpatentable over Adams et al. for locus AA311795, and further in view of Sibson et al., WO94/01548, for the reasons set forth in the last Office Action, paper No. 12, at page 8.

Applicants argument in paper No. 13 has been fully considered, but is not deemed persuasive for reasons below.

At page 9 of the response, applicants argue that because of the exclusion of Adams's nucleotide sequence from claim 5, it would not have been obvious to arrive at the present invention because Sibson merely discloses the desirability of generally placing a cDNA into an expression vector to express the encoded protein. This argument is not persuasive because the rejection was made based the limitations in *claims 1-4*, such as fragments of SEQ ID NO:1, and they do not dependent from claim 5. Therefore, amendment of claim 5 does not change the issue in the rejection of claims 1-4.

With respect to claims 7-9, they read on a composition comprising the protein in the above rejected claims 1-4 and a carrier. As it is well known in the art that a protein composition usually comprises the protein itself and other agent(s), such as dissolving solutions. Dissolving solutions, such as water, buffers, or media, meet the limitation of being "a pharmaceutically acceptable diluent". Therefore, the composition is obvious over the protein. As to the

limitations of intended use in claims 8 and 9, they do not alter the nature of the composition. Therefore, such claim limitation adds no patentable weight to said composition.

The above rejection would be reinstated for claim 10 if new matter rejection of the claim is removed.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/28/03